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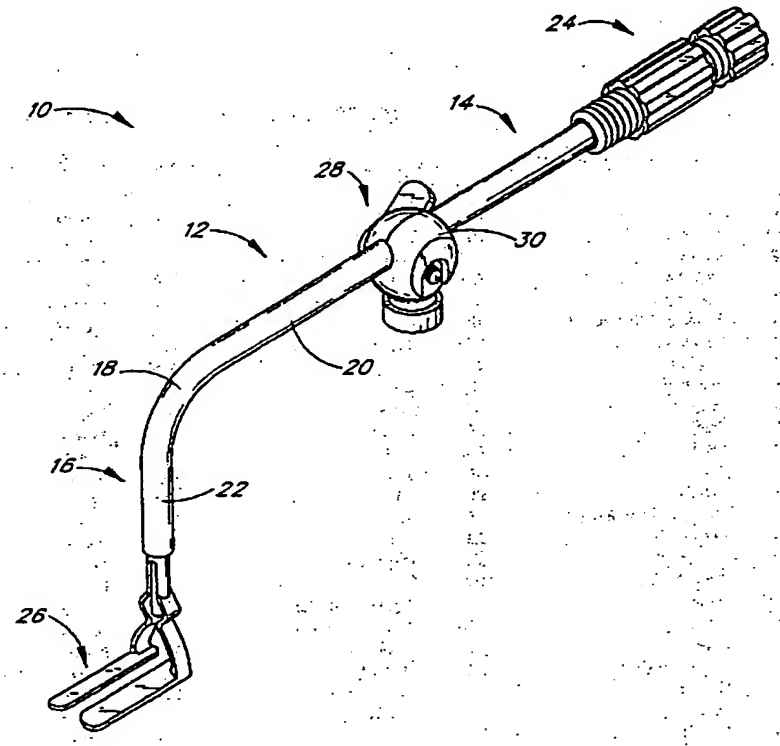
With international search report.

(54) Title: STABILIZER

(57) Abstract

The present invention is a tool (10) for stabilizing a portion of the heart upon which cardiac surgery is to be performed. The tool (10) includes an elongated shaft (12) with a distal end (14) which remains outside of the body of the patient, and a proximal end (16) which is inserted into the body of the patient. The tool (10) includes a control mechanism (24) attached to said distal end (14) of said shaft (12), and an engagement member (26) is attached to the proximal end (16) of the shaft (12). The engagement member (26) includes one or more prongs (142) which engage the heart proximate the location where the surgery is to be performed. The control mechanism (24) used to adjust the distance between the prongs (142), and the prongs (142) have a generally thin smooth portion which engages the heart.



STABILIZER

Background of the Invention

The present invention relates generally to the field of surgical instruments and, in particular, to a stabilizer used during heart surgery.

During a conventional surgical procedure, a mechanical retractor is often used to hold various organs and tissues away from the body part upon which the surgery is to be performed. By holding these other organs and tissues out of the way, the retractor provides access and visibility of the desired body part to the surgeon. The retractor is often held by the surgeon or the surgeon's assistant, which quickly becomes a very tiring procedure because the retractor must be held in a relatively stationary position and the retractor must be carefully used so as not to damage the tissues or organs surrounding the surgical site.

A retractor may be used during conventional surgery in which a relatively large incision is made in the patient and the retractor is inserted through the large incision, or a retractor may be used during laparoscopic surgery in which one or more relatively small incisions are made in the patient and the retractor is inserted through the small incision. A conventional retractor used during laparoscopic surgery is disclosed in U.S. Patent No. 5,152,279 issued to Wilk. The Wilk patent discloses a retractor including an elongated frame and a substantially rigid retractor member movably mounted to the frame. The Wilk patent explains that during surgery, some internal organs or tissues are disposed under other organs when the patient is lying on his or her back (a normal posture during surgery). The overlying or adjacent organs and tissues must be lifted or displaced prior to operating on the desired organ. The Wilk patent discloses using the substantially rigid retractor member to displace these overlying or adjacent organs to provide access to the desired surgical site. Thus, the Wilk patent discloses a retractor that pushes away the tissues and organs surrounding the surgical site.

Another retractor is disclosed in U.S. Patent No. 5,293,863 issued to Zhu, et al. The Zhu patent discloses a bladed endoscopic retractor for use during endoscopic surgery in which bladed instruments located inside the patient's body are manipulated by controls located outside the body. Specifically, the blades are movably connected at one end to the inside of a tubular body, and the other ends of the blades are free to retract the various organs and tissue. The Zhu patent explains the purpose of the retractor blades is to push the surrounding tissues and organs away from the operating area. The Zhu patent defines the movement of the neighboring tissues and organs in one direction by the bladed endoscopic retractor while another instrument performs the surgery on the desired tissue or organ as counter traction.

There is a need for a convenient and practical device which stabilizes the heart during cardiac surgery.

Summary of the Invention

The invention is generally related to a stabilizer for holding a portion of an organ or tissue in a relatively stable position while surgery is performed on that body part and, in particular, to a stabilizer used during cardiac surgery.

One aspect of the invention is a device which engages a portion of an organ upon which surgery is to be performed, and holding that portion of the organ in a relatively stable position. Advantageously, the invention is used

to the elongated body to allow the tool to be attached to a supporting member or surface such as another surgical instrument.

In yet another embodiment of the invention, the stabilizer comprises an elongated body with one or more prongs connected at one end. The prongs support a portion of the heart during cardiac surgery. Preferably, a conduit is connected to each of the prongs and a vacuum is selectively applied through the conduit to engage the outer surface of the heart with the prongs. The vacuum provides positive engagement of the prongs with a portion of the outside surface of the heart. Advantageously, the vacuum helps prevent slippage or movement of the heart relative to the prongs. Significantly, the vacuum helps prevent trauma and injury to the heart because less pressure is applied to the outer surface of the heart by the prongs.

In still another embodiment of the invention, a method for using the present invention comprises the steps of providing a stabilizer with an elongated body and one or more prongs connected at one end of the body, forming an opening in the chest of the patient, inserting a portion of the stabilizer through the opening, manipulating the stabilizer so that the one or more prongs engage the desired portion of the organ to be operated.

Advantageously, the device is constructed from a few simple components which provide quick and easy assembly and disassembly. This allows all or a portion of the device to be readily sterilized or disposed.

Brief Description of the Drawings

These and other features of the present invention will now be described with reference to the drawings of preferred embodiments, which are intended to illustrate and not to limit the invention, in which:

Figure 1 is a perspective view of the left side of a stabilizer in accordance with an embodiment the present invention;

Figure 2 is a perspective view of the right side of the stabilizer shown in Figure 1;

Figure 3 is an exploded perspective view of the stabilizer shown in Figure 2;

Figure 4 is an exploded perspective view of the stabilizer shown in Figure 1;

Figure 5 is a top, plan view of the stabilizer shown in Figure 2;

Figure 6 is a right side view of the stabilizer shown in Figure 2;

Figure 7 is a front end view of the stabilizer shown in Figure 2;

Figure 8 is a cross-sectional side view along lines 8-8 of Figure 2, illustrating the cam lever in a first position;

Figure 9 is a cross-sectional side view of the stabilizer shown in Figure 8, illustrating the cam lever in a second position;

Figure 10 is a partial exploded perspective view of the stabilizer shown in Figure 1;

Figure 11 is a cross-sectional side view along lines 11-11 of Figure 5;

Figure 12 is a perspective view of another embodiment of a stabilizer;

Figure 13 is a cross-sectional side view along lines 13-13 of Figure 12;

Figure 14 is a cross-sectional side view of a portion of another embodiment of a stabilizer;

Figure 15 is a bottom view of a portion of the stabilizer shown in Figure 14, illustrating the feet;

the surgeon to bend the sections 20, 22 or elbow 18 into the desired configuration. The diameter of the body 12 is between about 1/4 inch (.5 cm) and 3/4 inch (2 cm), and more preferably about 1/2 inch (1 cm); and the walls of the body 12 are relatively thin to form a relatively thin-walled tube. It will be understood the size and dimensions of the body 12 may vary according to the type of material used to construct the body, and the intended use of the stabilizer 10.

Additionally, all or a portion of the body 12 may be constructed from shape memory alloys which are materials, either plastic or metal, that are flexible at one temperature and generally rigid at another temperature. Desirably, the alloy is flexible at a temperature greater than body temperature (e.g., over 50°C) and generally rigid at about body temperature (37°C) or lower. Thus, the body 12 may be constructed from shape memory alloys which are generally rigid to facilitate inserting the stabilizer 10 into the body of the patient, but flexible when heated above body temperature. This allows the surgeon to heat and shape the body 12 into a configuration most suitable for use during surgery, and then cooled so that the body 12 maintains the desired shape.

The first section 20, second section 22 and elbow 18 may be individual members which are interconnected to form the body 12, but the body 12 is preferably integrally formed as a single member for increased strength and rigidity. The length of the first section 20 is preferably between about 4 inches (10 cm) and 18 inches (45 cm), and more preferably about 12 inches (30 cm). The length of the second section 22 is preferably between about 1 inch (2.5 cm) and 4 inches (10 cm), and more preferably about 2 inches (5 cm). Of course, the sections of the body 12 may be longer or shorter depending upon the desired used of the stabilizer 10 and the physical characteristics of the patient. Additionally, the body 12 may comprise multiple interconnected members or telescoping members which allow the length of the body 12 to be adjusted.

The stabilizer 10 also includes a control mechanism 24 connected to the distal end 14 of the body 12 and an engagement member 26 connected to the proximal end 16 of the body 12. As described below, the control mechanism 24 controls the movement of the engagement member 26 which is located at the opposite end of the body 12. The stabilizer 10 also includes a connector 28 located between the control mechanism 24 and the engagement member 26. The connector 28 allows the stabilizer 10 to be connected to a support member or surface such that the stabilizer is held in a relatively stationary position. The connector 28 advantageously allows the stabilizer 10 to be readily positioned in a variety of desired locations, and then locked into the desired location.

As best seen in Figures 3 and 4, the connector 28 comprises a universal joint 30 attached to the first section 20 of the body 12, but the connector may also be attached to the second section 22 or elbow 18 of the body 12. The universal joint 30 includes a clip 31 for mounting the stabilizer 10 to a support member such as a rib retractor (not shown). As seen in Figures 6, 8 and 10, attached to the bottom portion of the clip 31 are feet 32 for connecting the stabilizer 10 to the support. The feet 32 have an angled outer face 32A and the feet are spaced apart by a distance 32B. The feet 33 are preferably constructed from a slightly flexible material, such as plastic, to allow the feet to slightly deform when the clip 31 is attached to the support. This allows the feet to be connected to the retractor by a "snap" fit or interference fit. It will be appreciated that there are many different ways to connect the clip 31 to the support, and the feet 32 may have many different sizes and configurations

A cam lever 100, which contains an aperture 102 through which the end of the first shaft 84 is inserted, is positioned between the first clamp housing 60 and the clip 90. The cam lever 100 includes a handle 104 with a curved portion 105 which is configured to fit around the exterior surface of the housing 60. The cam lever 100 is movable between a first position in which the universal joint 30 allows the body 12 to pivot about the pivot pin 48 and the length of the body 12 to move; and a second, locked position in which the body 12 is securely held at a desired position and the body 12 cannot rotate about the pivot pin 48.

As seen in Figures 8 and 9, the cam lever 100 is connected to the cam lock 80 and the cam lock 80 is pivotally mounted within the housings 60 and 66. As seen in Figure 8, in the first position, the rectangular portion 82 of the cam lock 80 is positioned between the pivot pin 48 and body 12, but the rectangular portion of the cam lock does not engage either the pivot pin 48 or the body 12. Thus, this first position allows the universal joint 30 to rotate and the body 12 is movable within the universal joint.

As seen in Figure 9, in the second position, the cam lever 100 has been rotated which causes the rectangular portion 82 of the cam lock 80 to pivot at about a 90° angle relative to the first position. In this second position, the rectangular portion 82 engages both the upper surface 50 of the pivot pin 48 and the body 12 to prevent rotation of the universal joint 30 and movement of the body 12 within the universal joint 30. As seen in Figure 9, the deformable surface of the rectangular portion 82 has deformed to create an interference fit with the body 12 and the pivot pin 48. Thus, in the second position, the cam lock 80 locks the body of the stabilizer 10 in the desired position.

As best seen in Figures 10 and 11, the control mechanism 24 includes a connecting member 110 with external threads 112 connected to the distal end 14 of the body 12. The threads 112 may be formed integrally with the body 12, or the connector 110 may be attached to the body by any known fastener, such as glue or epoxy. A height adjustment knob 114 with internal threads 115 is threadably connected to the external threads 112 of the member 110. The height adjustment knob 114 includes a plurality of radially outward extending ridges 116 configured to facilitate grasping of the knob 114 by the surgeon. As shown in Figure 9, the ridges 116 extend generally parallel to the length of the height adjustment knob 114, but the ridges may also have any other desired orientation, and a textured or smooth surface may also be utilized to allow the surgeon to rotate the height adjustment knob 114. The height adjustment knob 114 includes an extension 118 with external threads 120 extending from the end of the knob 114 opposite the body 14.

The external threads 120 of the extension 118 are configured to engage the internal threads 122 of a dial 124. The dial 124 includes a plurality of radially outward extending ridges 126 configured to allow grasping of the dial 124 by the surgeon. As shown in Figure 10, the ridges 126 extend generally parallel to the length of the dial 124, but the ridges may also have any other desired orientation, and a textured or smooth surface may also be utilized to allow the surgeon to rotate the dial 124. As described below, the control mechanism 24 allows the height of the engagement member 26 to be adjusted and allows the engagement member to be manipulated by controls located away from the surgical site. Preferably, the controls are located outside the body for easy access and manipulation of the controls by the surgeon.

blood flow through the artery. Alternatively, the prongs 142 may be configured to engage or apply pressure to the coronary artery such that blood flow through the artery is constricted or stopped.

The prongs 142 have a curved upper portion 150 which forms a generally S-shaped member, but it will be appreciated that the upper portions 150 may be formed into numerous desired shapes and may be of different sizes. The prongs are normally biased into a closed position in which the prongs 142 and upper portions 150 are located generally proximate to each other. This facilitates inserting the prongs 142 through the incision and into the patient. In the closed position, the spreader 138 is positioned above the upper curved portions 150 of the prongs 142. When the surgeon rotates the dial 124 and the spreader 138 move downwardly, the spreader engages the curved portions 150 of the prongs and the spreader 138 forces the prongs apart. This also moves the feet of the prongs 142 apart. Alternatively, when the surgeon desires to move the prongs into the closed position, the surgeon rotates the dial in the opposite direction and the spreader 138 is lifted such that it no longer engages the curved portions 150 of the prongs.

The prongs 142 are desirably sufficiently rigid so as not to excessively bend or flex when engaging the outer surface of the heart. This allows the prongs to securely engage the heart. On the other hand, the prongs may be slightly flexible to avoid damaging or irritating the surface of the heart. The prongs 142 may be stamped out of thin pieces of metal, constructed from stainless steel or other alloys, or molded from various types of plastics or composites.

In another embodiment of the invention, as shown in Figures 12 and 13, a conduit 160A and 160B is attached to each of the prongs 142A and 142B. The conduits 160A and 160B include one or more apertures 162 which are aligned with one or more apertures 164 that extend through each of the prongs 142A and 142B. Preferably, there are three apertures 162 in each conduit 160A and 160B that are aligned with three apertures 164 in the prongs 142A and 142B. More preferably, as seen in Figure 13, the apertures 164 in the prongs 142A and 142B are tapered for secure engagement of the outer surface of the heart with the prongs. Of course, the conduits 160 and the prongs 142 may have a different number of apertures and the apertures may have a variety of different configurations.

The conduits 160A and 160B are connected to a vacuum source 166 by a conduit 162. Suction from the vacuum source is used to engage the prongs 142 of the stabilizer 10 with the outer surface of the heart. Advantageously, the prongs 142 of the stabilizer 10 do not have to be forcibly pressed into the outer surface of the heart, and the heart is less likely to be irritated or lacerated, because the vacuum creates a positive engagement between the prongs 142 and the outer surface of the heart. Additionally, the vacuum helps prevent slippage or movement of the heart and the prongs 142 may also be smaller in size, which results in less contact area and trauma to the heart because the vacuum creates a secure engagement with the desired portion of the heart. Desirably, the surgeon and/or assistant controls whether the vacuum is on or off and the amount of the vacuum.

In yet another embodiment of the invention, as shown in Figures 14 and 15, the stabilizer 10 includes a foot portion 170 connected to the proximal end 16 of the arm 12. The foot portion 170 includes a first foot 172 and a second foot 174 connected by an attachment member 176. The attachment member 176 has a first generally

portion 170, the rotatable member is adjusted such that first end 194 of the inner tube 192 is forced against the ball 184 to prevent the ball from moving. This causes the foot portion 170 to be held in a stationary position. In particular, because the ball 184 has a low-to-medium hardness, the sharp edges of the inner tube 192 securely engage or "bite" into the ball in order to resist movement of the ball. Therefore, the surgeon can position the foot portion 170 in the desired location and lock the feet in place.

This ball and socket joint advantageously permits the stabilizer arm 12 to have a wide variety of configurations. Specifically, the outer tube 188 can be formed into the desired shape; for instance, with one or more curved or angled sections. The flexible inner tube 192 and flexible member 194 then adapt to the configuration of the outer tube 188. Thus, the stabilizer can be shaped so that the feet engage the desired position of the heart.

Additionally, although not shown in the accompanying figures, the first end 190 of the outer tube 188 that contains the ball 184 could be removable. That is, the portion of the outer tube 188 that contains the ball 184 could be disconnected from the remaining portion of outer tube. Significantly, this allows the ball 184 and foot portion 170 to be repaired, replaced or interchanged with another ball and foot portion with different configuration. This removable section also facilitates reuse and sterilization of the stabilizer.

In another embodiment of the invention, as shown in Figures 16 and 17, the stabilizer 10 includes an adjustable foot portion 190 connected to the proximal end 16 of the arm 12. The foot portion 190 includes a first foot 192 and a second foot 194 which are connected to arms 196 and 198 respectively. The arms 196 and 198 are connected to a spring retainer 200 which is fixed to an outer tube 202. The outer tube 202 may be an integral part of the arm 12, or attached to the proximal end 16 of the arm. The spring retainer 200 is a resilient member which normally biases the foot portion 190 into an open or spaced apart position. Slidably mounted within the outer tube 202 is an inner tube or sleeve 204. The inner tube 204 includes slots 206 and 208 which allow the spring retainer 200 to be connected to the outer tube 202 and the slots allow movement of the inner tube within the outer tube. The distal end 210 of the inner tube 204 is attached to an element (not shown) which extends through the arm 12 of the stabilizer 10. The other end of the element is attached to a rotatable member located at the distal end of the outer tube 202. The rotatable member is configured such that when the member is rotated in one direction, it pushes the element and the attached inner tube 204 towards the foot portion 190. When the rotatable member is rotated in the opposite direction, it moves the element and the inner tube 204 away from the foot portion. The element is preferably a flexible, non-compressible cable which freely moves within the outer tube 202.

As shown in Figure 16, the inner tube 204 is in its normally closed position with the feet 192 and 194 positioned near each other. In this position, the inner tube 204 is located near the foot portion 190 and the arms 196 and 198 are positioned within the inner tube. The feet 192 and 194 may also be placed in an open position as shown in Figure 17. In the open position, the inner tube 204 is moved away from the foot portion 190 and the spring retainer 200 forces the arms 196 and 198 and feet 192 and 194 apart.

Advantageously, the stabilizer 10 can easily be inserted into the body while the feet 192 and 194 are in the closed position. After the proximal end 16 of the arm 12 is placed in the body, the surgeon can then turn the rotatable member to spread the feet 192 and 194 into the open position. Desirably, the surgeon can adjust the

WHAT IS CLAIMED IS:

1. A stabilizer for supporting a portion of the heart during cardiac surgery, comprising:

an elongated shaft having a distal end and a proximal end;

one or more prongs attached to said proximal end of said elongated shaft;

a control mechanism attached to the distal end of said elongated shaft, said control mechanism allows the location of said prongs to be adjusted; and

wherein said prongs engage the heart proximate the location where the cardiac surgery is to be performed to hold the portion of the heart in a relatively stable position.

2. The stabilizer of Claim 1 wherein said prongs are adapted to engage a beating heart.

3. The stabilizer of Claim 1 wherein said prongs have a generally thin, flat portion to engage the heart.

4. The stabilizer of Claim 1 wherein said prongs have a generally smooth surface to engage the heart.

5. The stabilizer of Claim 1 further comprising a connector attached to said elongated shaft, said connector allowing the stabilizer to be attached to a supporting surface.

6. The stabilizer of Claim 1 further comprising a conduit attached to said prongs, said conduit connected to a vacuum, wherein said vacuum provides a force which positively engages said prongs with the heart.

7. The stabilizer of Claim 1 wherein said control mechanism adjusts a lateral distance between said prongs.

8. A tool for supporting an organ upon which surgery is to be performed, comprising:

an elongated shaft having a distal end and a proximal end, said proximal end being inserted into the body of the patient and said distal end remaining outside of the body of the patient;

a control mechanism attached to said distal end of said shaft; and

an engagement member attached to said proximal end of said shaft;

wherein said control mechanism is located outside the body of the patient and controls the movement of said engagement member.

9. The tool of Claim 8 wherein said engagement member includes one or more prongs, said prongs are configured to engage the organ proximate the location where the surgery is to be performed.

10. The tool of Claim 9 wherein said one or more prongs includes two prongs, said two prongs are biased into a first position wherein said prongs are positioned proximate to each other.

11. The tool of Claim 10 wherein said control mechanism adjusts the distance between said two prongs.

12. The tool of Claim 10 further comprising a spreader, said spreader movable to change the spacing between said two prongs.

13. The tool of Claim 12 wherein said prongs have a proximal end attached to said elongated shaft; wherein said spreader is inserted between said proximal ends of said prongs; and wherein movement of said control mechanism adjusts a distance between said prongs.

28. The stabilizer of Claim 27 wherein said prong is mounted to the proximal end of said elongated body such that said prong may be spaced apart from another prong to provide stabilization of the portion of the heart.

29. The stabilizer of Claim 27 further comprising a control mechanism attached to said distal end of said elongated shaft, said control mechanism controlling the movement of said prong.

30. The stabilizer of Claim 27 further comprising a conduit connected to said prong, said conduit connected to a vacuum source.

31. The stabilizer of Claim 27 wherein said prong is adapted to hold the portion of a beating heart in a relatively stable position for cardiac surgery.

32. A method of performing cardiac surgery, comprising:

creating an opening in the chest wall of a patient;

providing a stabilizer, comprising:

an elongated shaft having a distal end and a proximal end;

a control mechanism attached to the distal end of said elongated shaft; and

one or more prongs attached to said proximal end of said elongated shaft;

inserting a portion of the stabilizer through said opening; and

manipulating the stabilizer so that said prongs engage the heart proximate the location where the cardiac surgery is to be performed to hold the portion of the heart in a relatively stable position.

33. The method of Claim 32 further comprising the step of spreading said prongs to engage the heart.

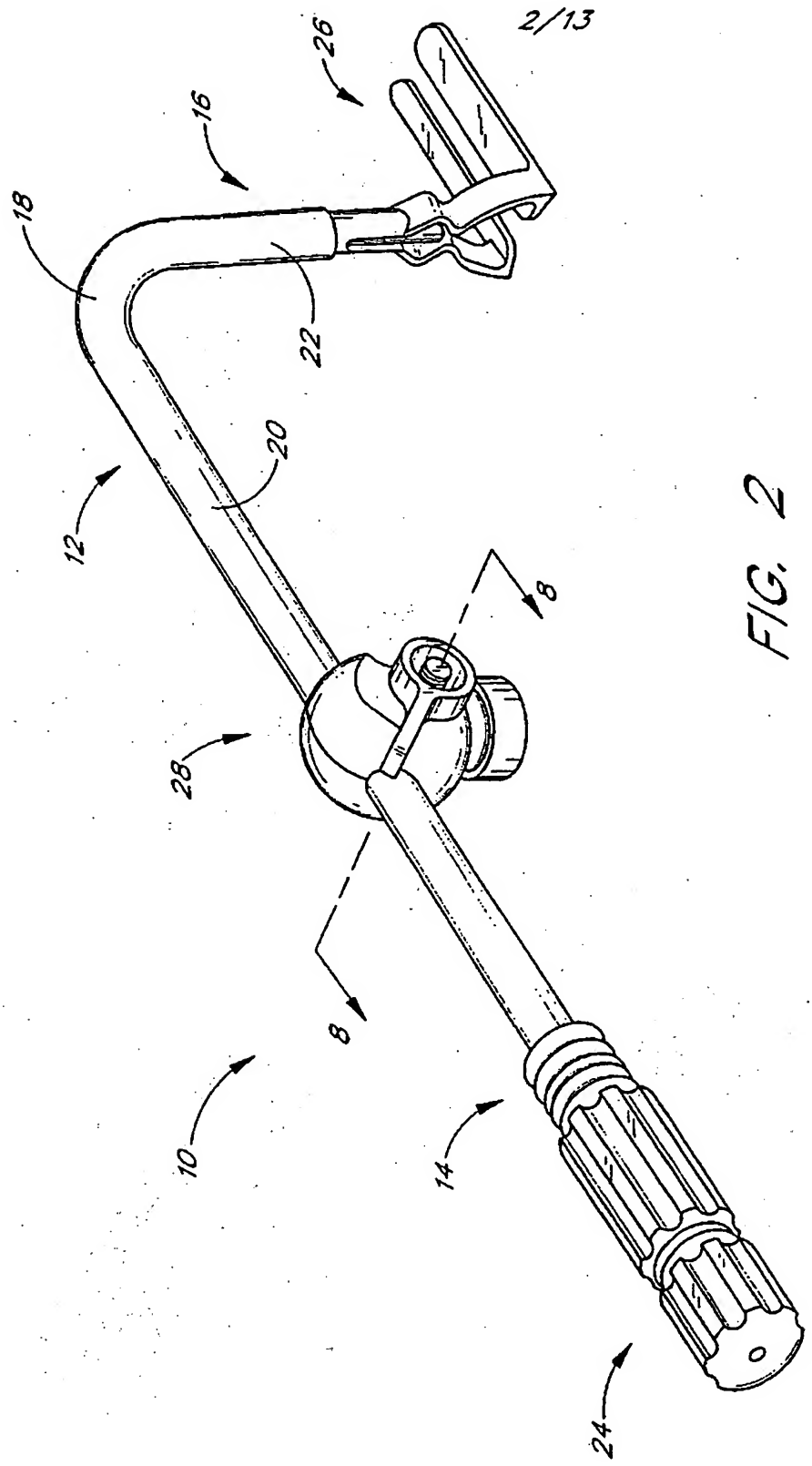


FIG. 2

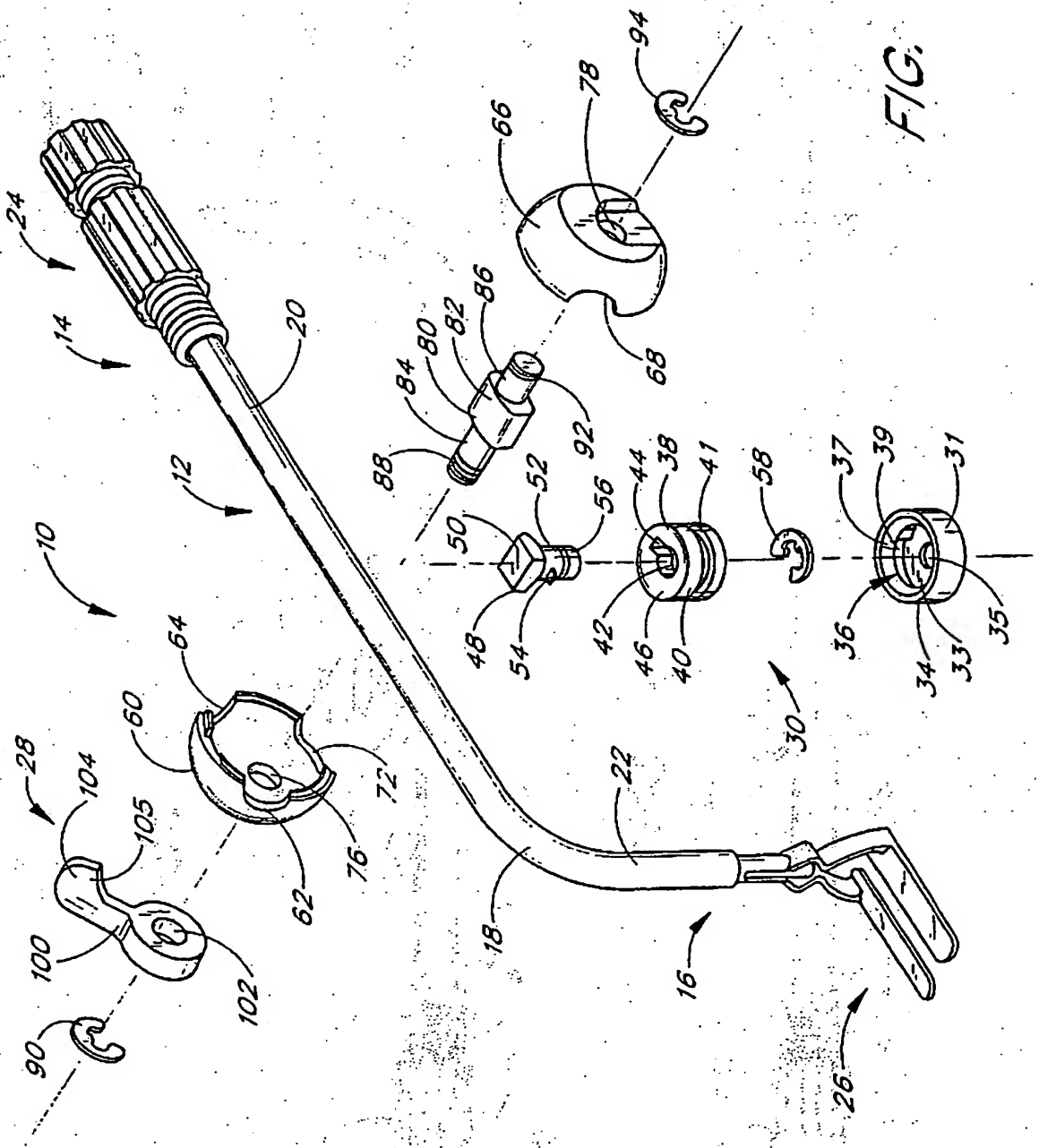

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FIG. 4

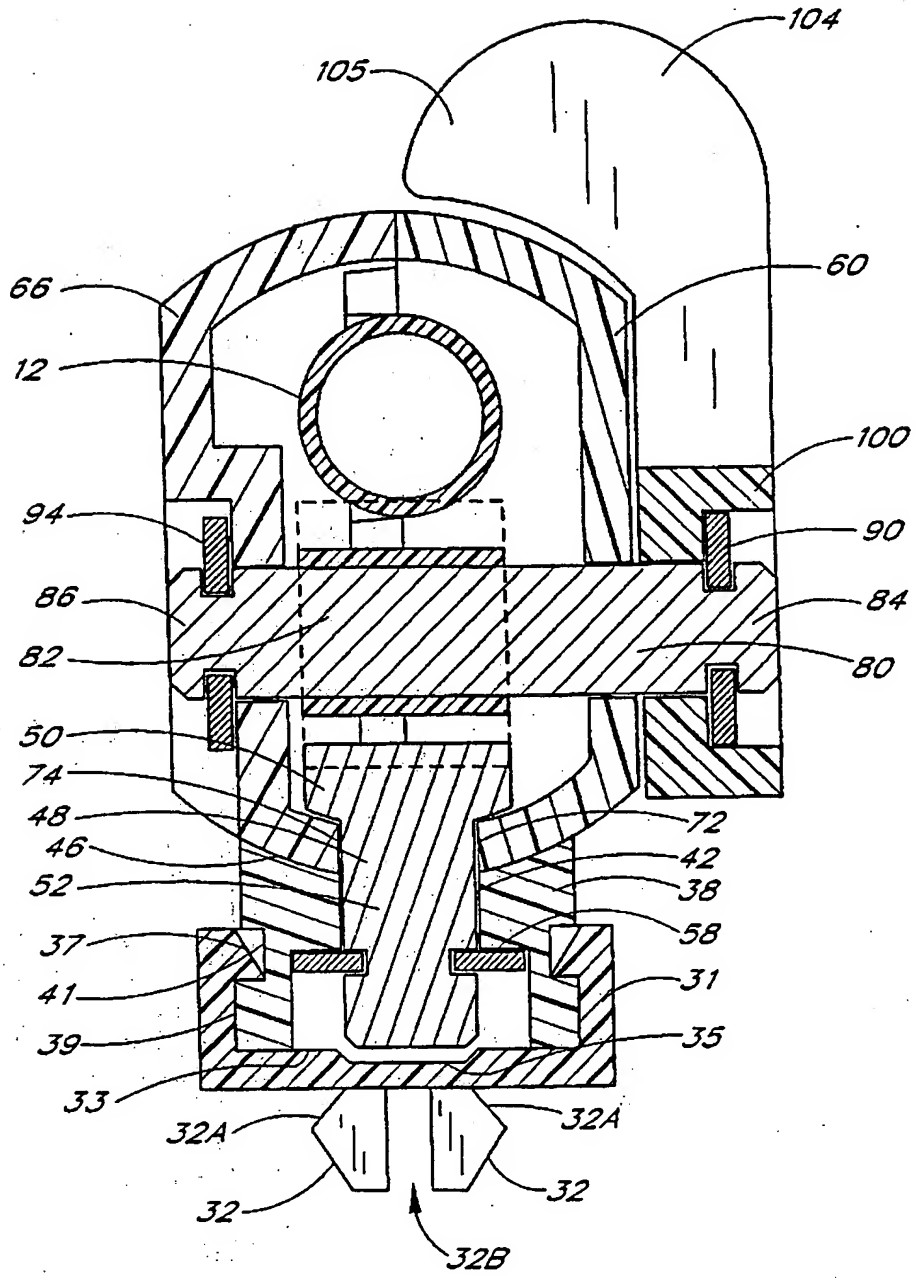
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FIG. 8

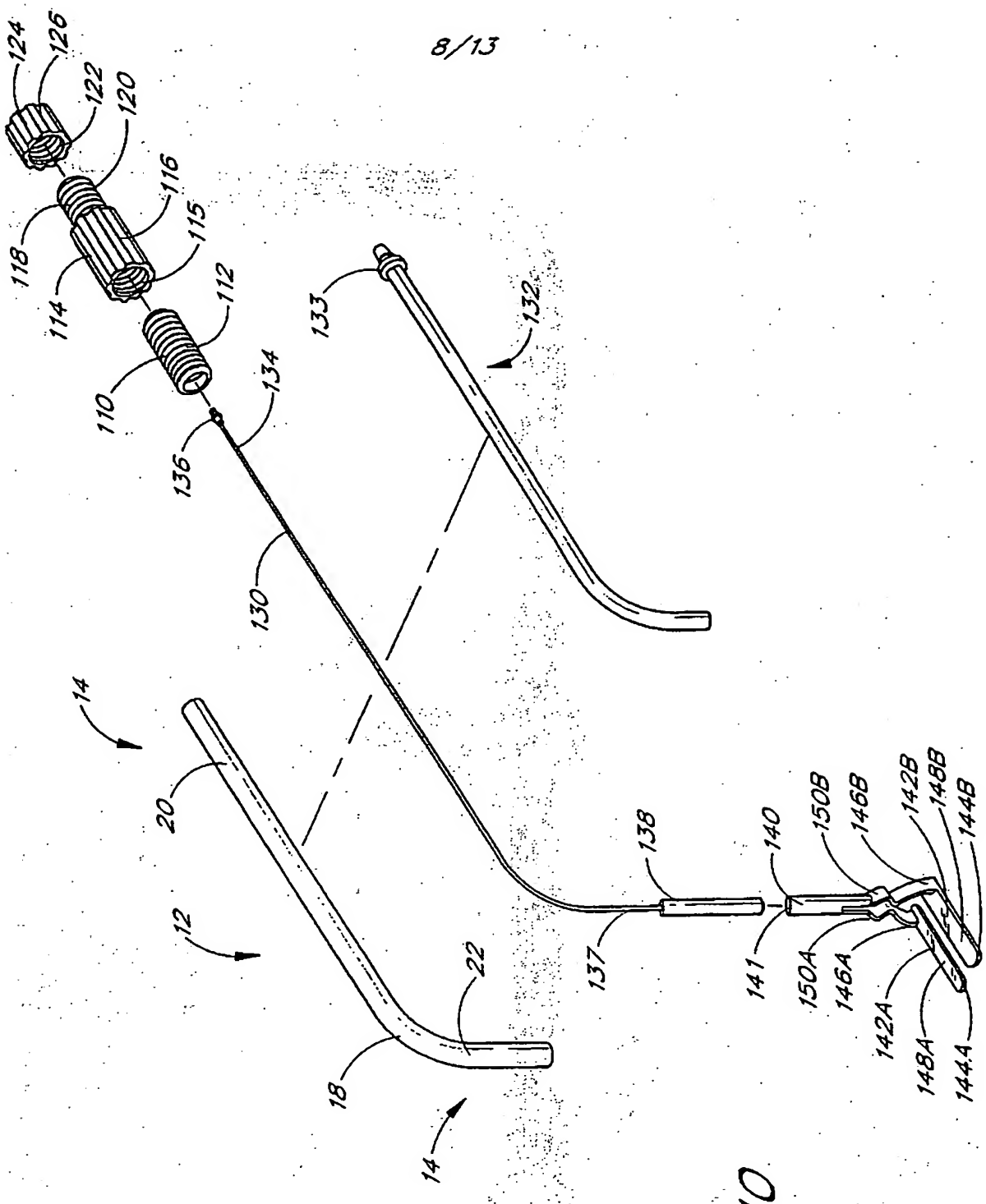
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FIG. 10

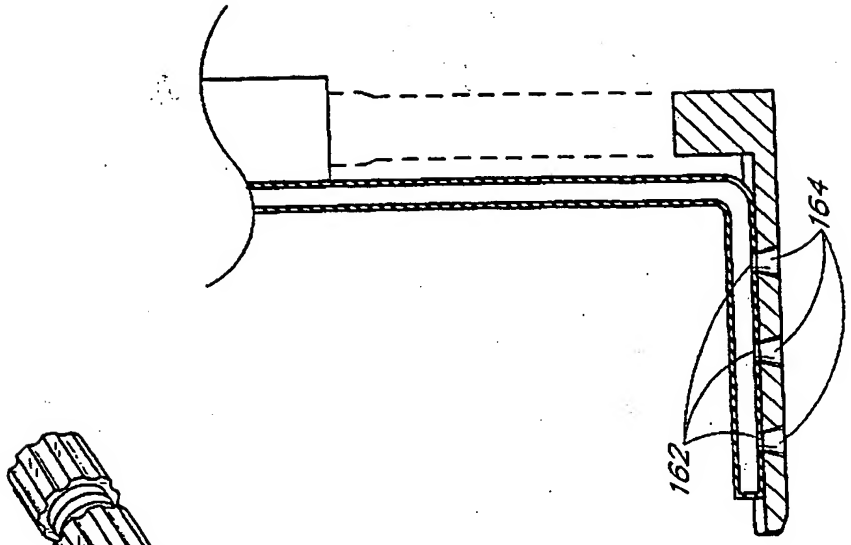
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FIG. 13

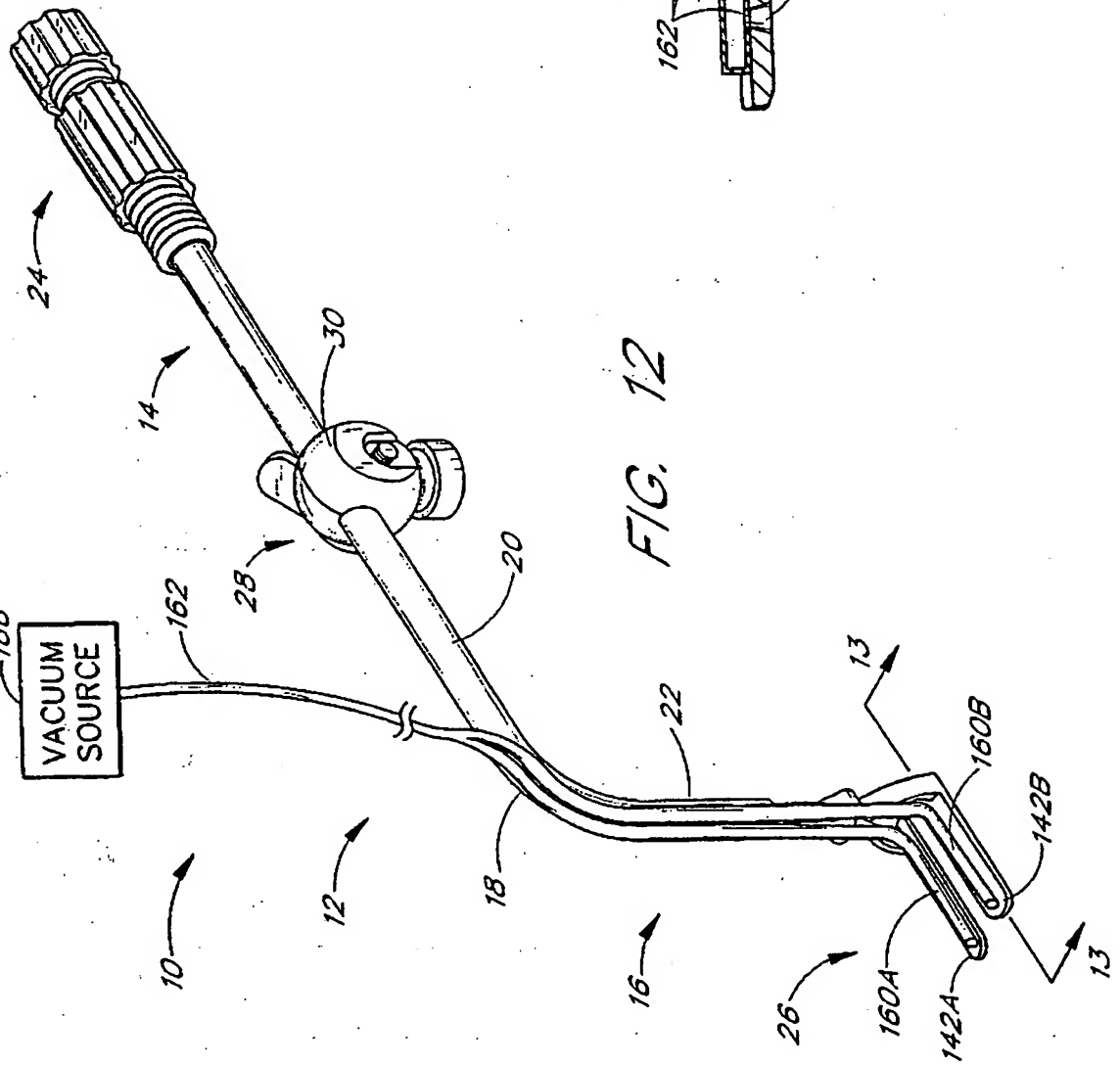
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FIG. 12

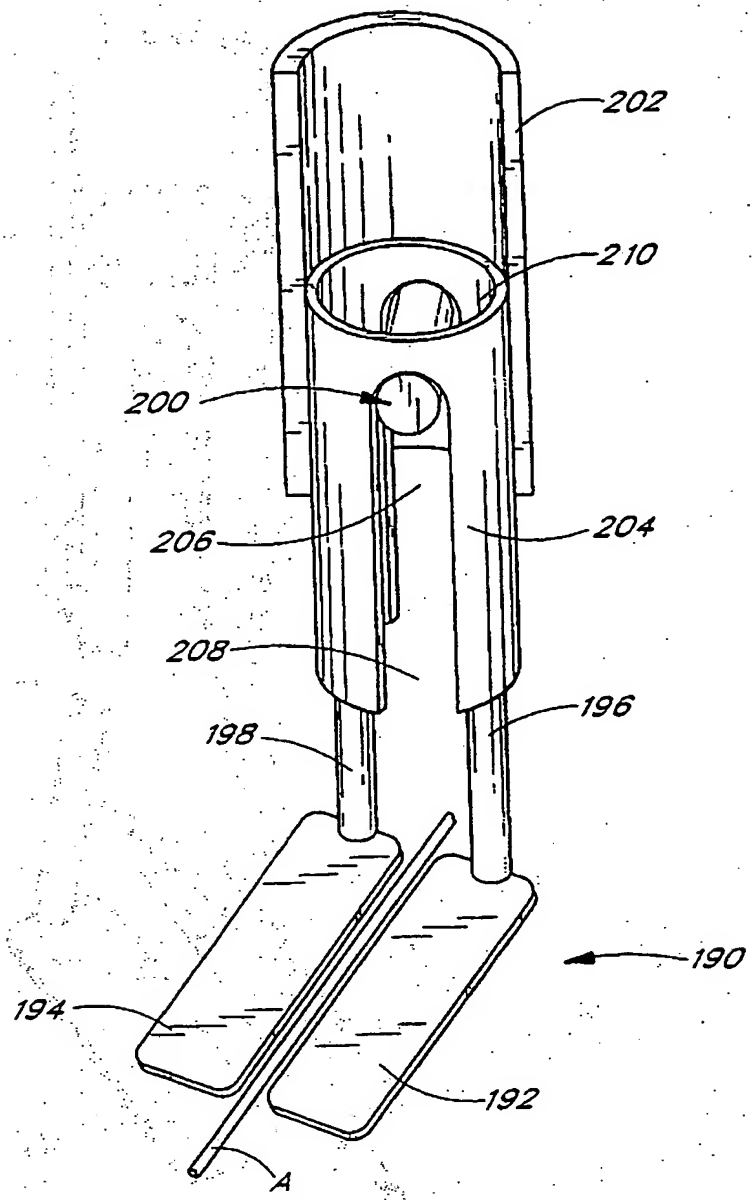

FIG. 16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/19928

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/28
US CL :606/205-208

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/205, 206, 207, 208

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,618,307 A (DONLON et al.) 08 April 1997, Figs. 1 and 2.	1-33
X	US 5,630,821 A (KLAAS) 20 May 1997, Figs. 1-5.	1-4, 6-33

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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